

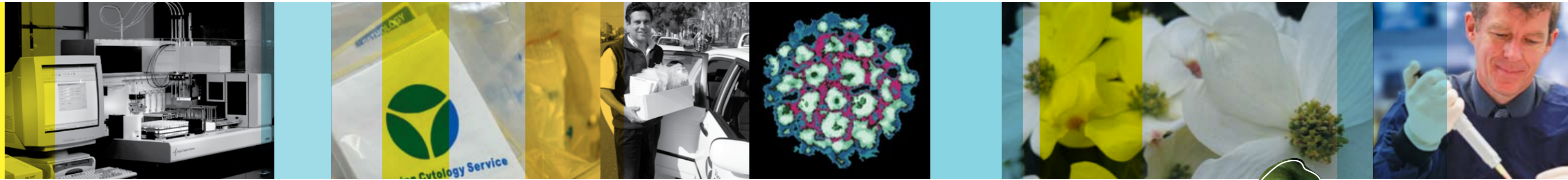
HPV testing

Digene Hybrid Capture 2

MOLECULAR MICROBIOLOGY AT VCS



HPV TESTING



What is the Digene Hybrid Capture 2 HPV test?

The Digene HPV test looks for 13 high-risk HPV types that are associated with the development of high grade lesions and cervical cancer. The test result is positive or negative for high risk types of HPV. Individual types of HPV are not separately identified.

When is this test indicated?

Under the revised NH&MRC Guidelines¹ this test is recommended as a "test of cure" after treatment for a **histologically confirmed** high grade squamous intraepithelial abnormality (CIN2, CIN3 or CIS).

A Medicare rebate has been available since November 1st 2005²

".....in a patient who:

- has received excisional or ablative treatment for high grade intraepithelial abnormalities of the cervix within the last two years;

or

- who within the last two years has had a positive HPV test after excisional or ablative treatment for high grade intraepithelial abnormalities of the cervix;

or

- who is already undergoing annual cytological review for the follow up of previously treated HSIL."²

If the test is being requested under these circumstances please ask the woman to **sign the Medicare assignment on the request form**. Complete a separate Medicare assignment form if one is not included on your request forms.

If the test is carried out under other circumstances then the woman should not sign the Medicare assignment section of the request form. VCS will charge her approximately \$64.

How do I collect the sample?

If you are taking a Pap test, you should collect this first. Then take an endocervical sample using the Digene sampler (Fig 1). The brush breaks and remains in the tube. VCS will supply these kits to your practice. Both Chlamydia and HPV tests can be run on this same endocervical sample.

It is not necessary to collect a ThinPrep specimen in order to do HPV testing. If you are collecting a ThinPrep specimen, we ask that you take a separate brush sample and send it in the Digene tube for the HPV test.

How long will the results take?

The test is performed in batches and the result will be available within one week.

Why not PCR?

The introduction of HPV testing as a "test-of-cure" following the treatment of women who have had a high-grade cervical lesion has inevitably led to a proliferation of tests being offered by laboratories, including the use of PCR (polymerase chain reaction).

VCS has decided to use the Hybrid Capture 2 test, which is clinically validated, rather than PCR. At the time of writing there is no commercially available PCR test for HPV that has been clinically validated.

Mark Stoler MD (well known for his work on HPV) has written of his concern regarding PCR testing for HPV. "There are large commercial labs that have homebrew HPV tests" [ref CAP Today September 2005] "particularly PCR-based tests, and they are not validated."

It is vital that a test used in these circumstances is not only clinically sensitive, but also specific. A lack of specificity can lead to false positive results. The Hybrid Capture 2 test is the only test for cervical high-risk HPV types that has been clinically validated and approved by the FDA.

Where can women get more information about HPV?

Information and resources are available from Papscreen Victoria at www.papscreen.org.au

Figure 1



Summary

TEST	Human Papillomavirus
SAMPLE	Digene brush and tube (Fig 1)
SITE	Endocervix
COST	Medicare rebatable under circumstances described*. The request form must be signed otherwise there is a charge of around \$64.00 to the woman
RESULT	Within 1 week

1 "Guidelines for the Management of a Symptomatic Women with Screen Detected Abnormalities", published by the NH&MRC 2005.
2 Medicare Schedule Benefits Book, Australian Government, Department of Health and Ageing, 1 May 2006.



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